HARMONIZING LOCAL PV ACTIVITY TO IMPROVE EFFICIENCY

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DISCLAIMER

I am an employee of Bionika Pharmaceuticals

I have about 25 years regulatory affairs & pharmacovigilance practice

Previously, I spent 5 years in chemical business

This presentation represents my personal view and is not necessarily the position of Bionika Pharmaceuticals

CONTENTS

- Local QPPV
- More niche look towards a local scale – the Balkan non-EU countries
- Managing medicinal products and medical devices in the same database
- How to overcome differencies in regulation across local regions
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LOCAL QPPV

- Differencies in regulation
- PV knowledge
- Training
- Quality Management System
- Knowledge and understanding of English language
- Audits (internal/external)

COUNTRIES OF INTEREST

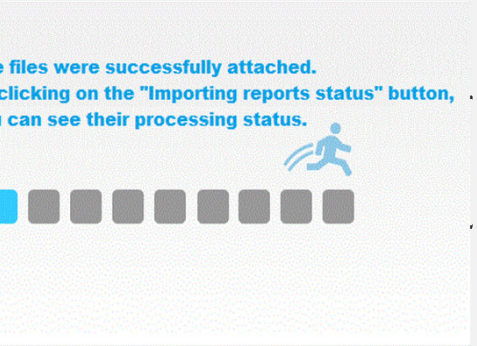
- EU/EEA - Eudravigilance
- Macedonia, Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo

LOCATION

Image source:
https://images.app.goo.gl/CfawXSc6rto4wLjH7

PV REGULATION - REGIONAL DIFFERENCIES

- **Macedonia** – PV & RA can be the same local responsible person;



- despite electronic submission of ICSRs, XML E2B(R3) format is preferred; paper in exceptional cases
- E2B(R2) can be converted to E2B(R3) in the system and vice versa
- serious (15 days) and non-serious (90 days) ICSRs from the country, serious and unexpected non-serious outside
- ICSRs can be submitted both by HCPs & patients
- Local MAH

PV REGULATION - REGIONAL DIFFERENCIES

- **Serbia** – PV local responsible person;

  - paper (rarely) & electronic submission of ICSRs

  - serious (15 d.) and non-serious (90 d.) ICSRs from the country, serious outside, except ICSRs already submitted in EudraVigilance and Upsala Monitoring Centre

  - ICSRs can be submitted both by HCPs & patients

  - RMP submission: obligatory

  - Local MAH

PV REGULATION - REGIONAL DIFFERENCIES

- **Montenegro** – PV & RA can be the same local responsible person;

  - paper & electronic submission of ICSRs

  - serious (15 d.) and non-serious (90 d.) ICSRs *local*

  - ICSRs can be submitted by HCPs & patients

  - RMP submission: obligatory

  - MAH can be from EU after EU accession /Law from 2020/ 2026

PV REGULATION - REGIONAL DIFFERENCIES

- **Kosovo** - PV local responsible person;

  - electronic submission of ICSRs only from 11.2019

  - serious (15 d.) and non-serious (90 d.) ICSRs *inside/outside*

  - ICSRs can be submitted only by HCPs

  - MAH: foreign MAH or the manufacturer

PV REGULATION - REGIONAL DIFFERENCIES

- **Albania** - PV & RA can be the same responsible person;

  - electronic submission of ICSRs: e-mail or web-page http://akbpm.gov.al/formulate-raportimi (Albanian language)

  - serious (15 d.) and non-serious (90 d.) ICSRs *local*

  - ICSRs can be submitted both by HCPs & patients

  - MAH: foreign MAH or the manufacturer

PV REGULATION - REGIONAL DIFFERENCIES

- **Bosnia & Herzegovina** – PV local responsible person;

BOSNA I HERCEGOVINA
AGENCIJA ZA LIJEKOVE I MEDICINSKA SREDSTVA
БОСНА И ХЕРЦЕГОВИНА
АГЕНЦИЈА ЗА ЛИЈЕКОВЕ И МЕДИЦИНСКА СРЕДСТВА

- paper & electronic submission (03.2019) of ICSRs
- serious and non-serious unexpected ICSRs from the country, serious unexpected outside (15 d.)
- ICSRs can be submitted both by HCPs & patients (paper)
- PSUR submission through e-portal: from 01.04.2020 is mandatory
- PSUR submission (MA): 1st year on 6 months, following 2 years once/year, after that once every 3 years (*all countries*)
- RMP submission: obligatory from 19.08.2021
- Local MAH

MEDICINAL PRODUCTS & MEDICAL DEVICES - SAME DATABASE

- **Medicinal products /Directive 2001/83/EC**

- **Medical devices – CE /Regulation (EC) 2017/745 (MDR);**
  MDCG 2025-10
  Notified body

- **Combination products:**

  - *Single-entity*: injectable pens or inhalers
  - *Co-packaged*: single pack or supplied as unit to be used/combined before administration/use
  - *Cross-labelled*: packed separately, but acc. to the label intended to be used together

MEDICINAL PRODUCTS & MEDICAL DEVICES - SAME DATABASE

- **Medicinal products** - SDEA (Safety Data Exchange Agreement)
  - QPPV
- **Medical devices**: - PMSA (Post Marketing Safety Agreement)
  - PRRC (Person Responsible for Regulatory Compliance)
- **Combination products**: - SDEA (integral medical device)
  Risks/Complications/Safety Management Plans
  - Mutual Recognition of Audits

HOW TO OVERCOME DIFFERENCIES ACROSS LOCAL REGIONS

- All countries are following EU Regulation, but there are differences in-between countries
- Macedonia is the only country from the region which has developed own data processing network and management system
- Trainings and education/learning are essential
- Following international standards
- Develop strategies to increase ADR reporting by all stakeholders

CONCLUSION

- It is expected that all countries will develop similar network and management system in the near future
- Changes in PV regulation will improve risk communication and signal detection – proactive & solution finding
- Regional aspects are moving towards Global aspects – Harmonisation
- Aligning PV Regulation across different countries can be benefitial to streamline PV activities and meet local needs

THANK YOU FOR YOUR ATTENTION !

QUESTIONS ?

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